

REMARKS

Claims 33, 35-37, 41, 42, 44-47, 52-55, 57-60, 62, and 64-78 are pending. Claim 64 is withdrawn from consideration by the Examiner. By this Amendment, claims 33, 42, 47, 52-54, 57-60, 62, 64, 67, 70-75, and 77 are amended, and claims 38-40, 43, 50, and 51 are canceled. Support for the amendments may be found in the original claims. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Personal Interview

The courtesies extended to Applicants' representative by Examiner Schlientz at the interview held November 3, 2011, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below, which constitute Applicants' record of the interview.

II. Rejection Under 35 U.S.C. §112

The Office Action rejects claim 39 under 35 U.S.C. §112, fourth paragraph, as being of improper dependent form. By this Amendment, claim 39 is canceled, rendering the rejection moot. Accordingly, withdrawal of the rejection is respectfully requested.

III. Rejection Under 35 U.S.C. §102

The Office Action rejects claims 33, 35-39, 42, 45-47, 50, 52-55, 57, 59, 60, 62, 65-67, 70, 74, 75, and 78 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,654,362 to Schulz et al. ("Schulz"). By this Amendment, claims 38, 39, and 50 are canceled, rendering their rejection moot. With respect to the remaining claims, Applicants respectfully traverse the rejection.

Claim 33 is amended to include the subject matter of claims 40, 43 and 51, which were not rejected as being anticipated by Schulz. As agreed to by the Examiner during the

interview, amended claim 33 is not anticipated by Schulz. Claims 35-37, 42, 45-47, 52-55, 57, 59, 60, 62, 65-67, 70, 74, 75, and 78 depend from claim 33 and, thus, also are not anticipated by Schulz. Accordingly, withdrawal of the rejection is respectfully requested.

IV. Rejections Under 35 U.S.C. §103

The Office Action rejects: (1) claims 33, 35-47, 50-55, 57-60, 62, and 65-78 under 35 U.S.C. §103(a) as having been obvious over Schulz in view of U.S. Patent No. 6,503,519 to Sakuta ("Sakuta"); and (2) claims 33-62 under 35 U.S.C. §103(a) as having been obvious over U.S. Patent No. 5,929,164 to Zhang ("Zhang") in view of Sakuta and Schulz. By this Amendment, claims 38-40, 43, 50, and 51 are canceled, rendering their rejections moot. With respect to the remaining claims, Applicants respectfully traverse the rejections.

Claim 33 recites, *inter alia*: " An anhydrous pharmaceutical composition comprising: at least one active ingredient in solubilized form, wherein the active ingredient is selected from the group consisting of Vitamin D and derivatives of Vitamin D, and is solubilized using at least one solvent, the solvent being from 1% to 50% by weight relative to the total weight of the composition; a silicone agent comprising at least one organopolysiloxane elastomer; a thickening agent different from the silicone agent, the thickening agent being a hydrocarbon-based wax chosen from glyceryl behenate and glyceryl dipalmitostearate, and mixtures thereof; and at least one agent for promoting the penetration of the active ingredient into the skin ... " (emphasis added).

The asserted combinations of references would not have rendered obvious claim 33 for at least the following reasons.

A. Schulz and Sakuta

Schulz is directed to thickened silicone oils in the form of silicone elastomers swollen into silicone gels, silicone pastes, or silicone powders. *See* Schulz, column 1, lines 15-17. As acknowledged by the Office Action, Schulz does not teach using glyceryl behenate or glyceryl

dipalmitostearate in its silicone gels. *See* Office Action, page 10. As further acknowledged by the Office Action, Schulz also does not disclose Vitamin D and derivatives of Vitamin D. *See* Office Action, page 8. Moreover, Schulz fails to teach the recited "agent for promoting penetration of the active ingredient in the skin," and "said solvent being from 1% to 50% by weight relative to the total weight of the composition."

**1. It Would Not Have Been Obvious To
Use The Recited Hydrocarbon-Based Wax**

The Office Action asserts that Schulz teaches octyl palmitate, an ester of a saturated fatty acid having 24 carbon atoms, in its compositions, and that emollients other than octyl palmitate may be used in the formulation, including ... lanolin wax. *See* Office Action, page 7. With respect to the thickening agent being a hydrocarbon-based wax chosen from "glyceryl behenate and glyceryl dipalmitostearate, or mixtures thereof," the Office Action asserts that "it was well-known ... that glyceryl behenate is a suitable emollient/skin conditioning agent for use in cosmetic formulation." *Id.* Notably, the Office Action provides no support for this assertion, and none of applied references teach using glyceryl behenate and glyceryl dipalmitostearate, and mixtures thereof, as the recited "thickening agent different from the silicone agent."

To the contrary, Sakuta, which is also silent regarding the recited "glyceryl behenate and glyceryl dipalmitostearate, and mixtures thereof," teaches that mixing waxy ingredients in a nonaqueous composition results in a tacky feel arising from the waxy ingredients that is difficult to eliminate even when silicone oils are employed. *See* Sakuta, column 1, lines 37-41. Further, the present disclosure addresses this problem, stating that it was "surprisingly" discovered that it is possible to use the hydrocarbon-based compounds as thickening agents, and in particular waxes, which are well known to be relatively incompatible with silicone

compounds. *See* specification, page 15, lines 14-17. Thus, the claimed composition was formulated contrary to such "common" knowledge.

Furthermore, the portion of Schulz relied on by the Office Action focuses on Schulz's antiperspirant formulation summarized in Table 1. Specifically, Table 1 contains octyl palmitate as the emollient. *See* Schulz, column 6, lines 66-67, Table 1. While Schulz states that "[e]mollient oils other than octyl palmitate can be used in the formulation, such as ... lanolin wax," lanolin wax is the only listed wax (other possible substitutes being oils), and it is listed as a possible "emollient oil." The lanoline wax is not taught as a "thickening agent," nor is there any disclosure of "glyceryl behenate and glyceryl dipalmitostearate, and mixtures thereof." Notably, glyceryl behenate and glyceryl dipalmitostearate are not "emollients" and, thus, would not have been substituted by a person of ordinary skill in the art for the octyl palmitate of Schulz's composition, as asserted by the Office Action.

2. It Would Not Have Been Obvious To Select Glycols Or Glycol Ethers As The Recited Agent For Promoting Penetration Of The Active Ingredient Into The Skin

In asserting that the asserted combination of references would have rendered obvious the recited "at least one agent for promoting the penetration of the active ingredient into the skin," the Office Action asserts that it would have been obvious to include, in Schulz's composition, a solvent, such as ethylene glycol and propylene glycol, as the "at least one agent for promoting the penetration of the active ingredient into the skin." However, not only does Schulz fail to teach the recited "active ingredient" (Vitamin D and derivatives of Vitamin D), but a person of ordinary skill in the art would not have been motivated to specifically select the specific compounds as the recited agent based on the teachings of Schulz.

Schulz teaches that "other types of solvents can swell the silicone elastomer." *See* Schulz, column 4, lines 55-56. Notably, these solvents are not taught to promote the

penetration of the active ingredient into the skin. Furthermore, to arrive at the desired compounds, the person of ordinary skill in the art would have to perform triple selection of almost infinite variants to arrive at the specific compounds, based on Schulz's disclosure.

First, as indicated in column 4, lines 59-65 of Schulz, a solvent can be selected from (i) organic compounds, (ii) compounds containing a silicone atom, (iii) mixtures of organic compounds, (iv) mixtures of compounds containing a silicone atom, and (v) mixtures of organic compounds and compounds containing a silicone atom. Thus, even if the person of ordinary skill in the art had selected "organic compounds" from this broad list of solvents, albeit with no particular incentive to do so, further selection would be necessary.

Thus, as a second selection, the person of ordinary skill in the art would have to select among aromatic hydrocarbons, aliphatic hydrocarbons, alcohols, aldehydes, ketones, amines, esters, ethers, glycol ethers, alkyl halides and aromatic halides. *See* Schulz, column 4, line 66 - column 5, line 2. Notably, each these families of compounds are exemplified by a great number of compounds. However, even if the person of ordinary skill in the art had selected, again without any particular incentive to do so, alcohols, glycols, or glycol ethers, there still would have been no reason or rationale to select, in the third selection, the specific compounds from those families, as suggested in the Office Action.

During the personal interview, the Examiner indicated that the list of possible alternative compounds provided in Schulz's disclosure is not so extensive as to be "infinite." Applicants disagree. As summarized above, the number of selections necessary in order to arrive at the specific compound required for the claimed anhydrous pharmaceutical composition is extensive, and Schulz (or the other applied references) provide no reason or rationale for the person of ordinary skill in the art to arrive at the specific compounds, contrary to the Office Action's assertions.

Moreover, even if the above selections were performed, as suggested by the Office Action, Schulz teaches that such solvents would have to replace the low molecular weight silicone oil used in the cross-linking reaction. *See* Schulz, column 1, lines 52-53. Specifically, Schulz states "a low molecular weight silicone oil or other solvent " (emphasis added). Thus, if such a selection of an alternative solvent was made, as proposed by the Office Action, there would have been no low molecular weight silicone oil in the composition of Schulz, as required in the anhydrous composition of claim 33.

For at least the reasons discussed above, the asserted combination of Schulz and Sakuta would not have rendered obvious claim 33. Claims 35-37, 41, 42, 44-47, 52-55, 57-60, 62, and 65-78 depend from claim 33 and, thus, also would not have been obvious over the asserted combination of references. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Zhang, Sakuta, and Schulz

Zhang is directed to methods for the quenching of post cure occurring in the thickening of siloxanes with silicone elastomers. *See* Zhang, column 1, lines 17-19. As acknowledged by the Office Action, Zhang at least fails to teach the inclusion of a hydrocarbon-based wax, let alone the recited glyceryl behenate or glyceryl dipalmitostearate, and mixtures thereof. *See* Office Action, page 12.

As discussed above, Schulz and Sakuta fail to cure this deficiency. Specifically, Schulz merely teaches incorporating emollients, one of such emollients possibly being lanoline wax, into a composition. However, claim 33 recites, and none of the applied references teach, using "glyceryl behenate or glyceryl dipalmitostearate, and mixtures thereof," as a thickening agent. While the Office Action alleges that glyceryl behenate is a suitable emollient/skin conditioning agent for use in cosmetic compositions, Applicants disagree (as discussed above). Specifically, glyceryl behenate or glyceryl dipalmitostearate,

and mixtures thereof and not known to be emollients and, thus, there would have been no reason for a person of ordinary skill in the art to include such compounds as emollients in the referenced compositions.

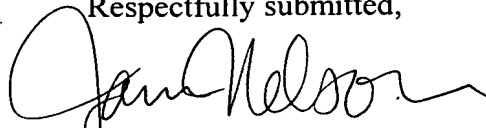
Thus, claim 33 would not have been obvious over the asserted combination of Zhang, Schulz, and Sakuta. Claims 35-37, 41, 42, 44-47, 52-55, 57-60, and 62 depend from claim 33 and, thus, also would not have been obvious over the asserted combination of references. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachments:

Petition for Extension of Time
Request for Continued Examination

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